K082041

5. 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is being submitted in accordance with 21CFR Part 807, Subpart E, Section 807.92.

Submitter's name and contact information
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AUG - 1 2008

Date prepared
30 June 2008

Trade Name, Common Name and Classification
Trade Name: FiatLux Visualize™
Common Name: Image Processing System, Radiology
Classification: Picture Archiving and Communications System, Class II

Substantially Equivalent Devices
FiatLux Imaging believes that FiatLux Visualize™ is substantially equivalent to other commercially available products, specifically:

- aycan Workstation OsiriX (K063470)
- BarcoView Voxar 3D (K060505)

Device Description
FiatLux Visualize™ is a medical device software application that provides multi-dimensional visualization of CT and MR medical images. FiatLux Visualize allows the user to select and retrieve a patient series, display and view the images and data, interactively manipulate the images to visualize anatomy and pathology, and analyze the images using a set of tools. It reads DICOM CT and MR images transferred using removable media or Microsoft Windows networking.

Intended Use:
FiatLux Visualize™ is a medical diagnosis software application that allows physicians, radiologists, medical technicians, nurses, and other trained medical professionals to select, review and analyze DICOM images acquired from CT and MR devices. It provides a suite of tools for 2D/3D reconstruction based on the input image dataset.

FiatLux Visualize software must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient

light conditions are consistent with the clinical applications. Mammographic and compressed images are not supported for viewing.

Substantially Equivalent Device Comparison

FiatLux Visualize™ and its substantially equivalent, commercially available devices allow for the media interchange and analysis of digital images acquired from CT and MR imaging devices. All devices support the DICOM protocol for reading images from the medical device data source.

Software

Software development for the FiatLux Visualize™ software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of medical device.

Technological Characteristics

FiatLux Visualize™ is software that is used with computer hardware to read, render and analyze diagnostic medical images in a user environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed.

Conclusions

The FiatLux Visualize™ software has similar intended uses as the substantially equivalent devices and has very similar technological characteristics to those devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, FiatLux Visualize™ is substantially equivalent to the commercially available devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FaitLux Imaging, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG - 1 2008

Re: K082041
Trade/Device Name: FiatLux Visualize™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 17, 2008
Received: July 18, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K082041

Device Name: FiatLux Visualize™

Indications for Use:

FiatLux Visualize™ is a medical diagnosis software application that allows physicians, radiologists, medical technicians, nurses, and other trained medical professionals to select, review and analyze DICOM images acquired from CT and MR devices. It provides a suite of tools for 2D/3D reconstruction based on the input image dataset.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082041